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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/913,811	09/24/1997	HIROKAZU SUGIHARA	356972020100	7552
25226	7590	05/03/2004	EXAMINER	
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018				BASKAR, PADMAVATHI
ART UNIT		PAPER NUMBER		
		1645		

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	08/913,811	SUGIHARA ET AL.
	Examiner Padmavathi v Baskar	Art Unit 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 30 January 2004.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 12, 14 and 16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 12, 14 and 16 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

1. Upon further review of the application, the finality of the previous Office action has been withdrawn. Applicant's response filed on 1/30/04 has been entered.

***Status of Claims***

2. Claims 12, 14 and 16 are pending in the application. No claims have been amended.

***Claim Rejection - 35 USC 103 withdrawn***

3. In view of applicant's arguments, the rejection of claims 12, 14 and 16 under 35 U.S.C. 103(a) as being unpatentable over Gahwiler et al (Neuroscience, 1982, 7; 1243-1256) in view of Giaever et al 1993 (U.S.Patent 5,187,096) is withdrawn.

***Claim Rejection - 35 USC 103 maintained***

4. The rejection of claims 12, 14 and 16 under 35 U.S.C. 103(a) as being unpatentable over Gahwiler et al (Neuroscience, 1982, 7; 1243-1256) in view of Gross et al. (J. of Neuroscience Methods 5: 13-22, 1982) is maintained as set forth in the previous office action.

Applicants' arguments filed on 1/30/04 have been fully considered but they are not deemed to be persuasive.

Applicant states that Gahwiler uses hippocampal cultures by cutting slices of rat brain and culturing them for 3-11 weeks and providing a tissue sample albeit many weeks later and therefore, it is not a chronic effect. Further, the prior art uses standard individual electrodes but not plurality of electrodes as required by the claim.

It is the examiner's position that the term "chronic" is a relative term with no lower time boundaries. Applicant cannot institute a lower bound time using a relative term.

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The term "chronic" is not defined by the claim; the specification does not provide a standard for ascertaining the requisite degree. Therefore, the prior art teaches a method of testing the chronic effect of compounds in a neural tissue culture. Please note the examiner has clearly indicated in the previous rejection that Gahwiler teaches a method of testing the effect of chemical substances (acetylcholine) on neuronal tissue (hippocampal sections) and measuring the electrical properties (see experimental procedures on page 1243 and 1244) before and after addition of said substances (see results and figures) and does not teach providing plurality of microelectrodes (i.e., the device or apparatus) to the tissue sample. However, Gross et al teach recording the electrophysiological potentials with electrodes integrated into the tissue culture plate would allow the long term monitoring of neuronal activity.

Finally, applicant states what confidence would ~~that~~ one of ordinary skill <sup>have</sup> ~~has~~ that the combined processes would produce useful results? Therefore, the references are ill combined and the rejection should be withdrawn.

MPEP 2143.02 states

OBVIOUSNESS REQUIRES ONLY A REASONABLE EXPECTATION OF  
SUCCESS.

The prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The examiner has established a prima facie ~~case~~  
~~of~~ <sup>ness</sup> obvious ~~rejection~~ using the apparatus (plurality of electrodes) in a method designed by Gross to teachings of Gahwiler et al to measure the electrical properties before and after addition of chemical substances to neural tissue sample. As explained previously Gross et al suggests that the apparatus disclosed is obviously designed for long term cultures. The motivation to use this apparatus and a method to achieve the

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obvious benefits is clearly suggested by Gross (see page 21, last paragraph). Thus the teachings of the prior art make the claimed invention obvious. However, it is not the examiner's burden to establish whether useful results obtained or not. Therefore, this rejection is maintained.

### ***New Rejections***

#### ***Claim Rejections - 35 USC 112, first paragraph***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 12,14 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 12 recites "chronic". However, the limitation " chronic" has no clear support in the specification or claims as originally filed. Applicant is advised to delete the term "chronic" in claim 12.

#### ***Claim Rejections - 35 USC 112, second paragraph***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 12, 14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 12 is vague in reciting "electrical properties" because it is not clear as such what are metes and bounds of the term "electrical properties?" Is it measuring an incomplete electrical waveform or something else? Does applicant intend to mean measuring a complete electrical waveform?

9. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padma Baskar Ph.D.

4/29/04

*Lynette R. F. Smith*  
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